DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

The Binding Site Group Ltd.
c/o Mr. Jay H. Geller
Authorized U.S. Representative
12100 Wilshire Boulevard, Suite 500
Los Angeles, CA 90025-7121

MAR 0 1 2010

Re: k082823
Trade/Device Name: Hevylite™ Human IgA Kappa Kit for use on the Siemens BN™ II
Hevylite™ Human IgA Lambda Kit for use on the Siemens BN™ II
Regulation Number: 21 CFR § 866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E Immunological Test System
Regulatory Class: Class II
Product Code: CFN, OPX, OPY
Dated: January 18, 2010
Received: January 27, 2010

Dear Mr. Geller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082823

Device Name: Hevylite™ Human IgA Kappa Kit for use on Siemens BN™II Systems

Indications for Use: This kit is intended for the in vitro quantification of IgA Kappa (combined α heavy and κ light chain) concentration in human serum on the Siemens Behring Nephelometer™ II (BN™ II). The test result is to be used with previously diagnosed IgA multiple myeloma, in conjunction with other clinical and laboratory findings.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD).

Reena Philip

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) 082823

Indications for Use

510(k) Number (if known): K082823

Device Name: Hevylite™ Human IgA Lambda Kit for use on Siemens BN™II Systems

Indications for Use: This kit is intended for the in vitro quantification of IgA Lambda (combined α heavy and λ light chain) concentration in human serum on the Siemens Behring Nephelometer™ II (BN™ II). The test result is to be used with previously diagnosed IgA multiple myeloma, in conjunction with other clinical and laboratory findings.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD).

Geeva Philip

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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